BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the: Application of		Michael D. Laufer et al.	
Serial No.	:	10/820,127	Confirmation No.: 8654
Filed	:	April 8, 2004	Group Art Unit: 3773
Entitled	:	METHODS AND DEVICES FOR TISSUE RECONFIGURATION	Examiner: Julian Woo
Docket No.	:	100873-266 END6430USCNT4	

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Ethicon Endo-Surgery, Inc., a Johnson & Johnson company. Ethicon Endo-Surgery, Inc. of Cincinnati, Ohio derives its rights in this application by virtue of an assignment of the application by NDO Surgical, Inc. to Ethicon Endo-Surgery, Inc. dated May 5, 2008. NDO Surgical, Inc. derived its rights of assignment in this application by virtue of an assignment of the application by Michael D. Laufer, Jeffrey C. Cerier, and Amos G. Cruz to NDO Surgical, Inc. recorded at Reel 010612, Frame 0524.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-21 and 24-53 are currently pending in the present application, Serial Number 10/820,127. Claims 22 and 23 are canceled. Accordingly, claims 1-21 and 24-53 are subject to appeal.

IV. STATUS OF AMENDMENTS

Appellant did not submit any claim amendments subsequent to the Office Action dated September 3, 2009.

A copy of the pending claims is attached as Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

1. Independent Claim 1

Independent claim 1 recites a tissue shaping instrument 200, comprising an elongated member 280, 290 having a distal effector portion (not identified by a reference number) and a proximal controlling portion 214, 254, 234, 264. *See, e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]); and FIGS. 25-29. The elongated member 280, 290 is of sufficient length to enable an operator to access an interior of a hollow organ of a subject with the distal effector portion while the proximal controlling portion 214, 254, 234, 264 remains outside of the subject. *See id.* A first tissue engaging device 220 is disposed on the distal effector portion of the elongated member 280, 290 and is operably connected to the

proximal controlling portion 214, 254, 234, 264. *See id.* Further, the first tissue engaging device 220 is structured for releasably engaging at least the inner surface of the hollow organ. *See id.*

A second tissue engaging device 240 is also disposed on the distal effector portion of the elongated member 280, 290 and is operably connected to the proximal controlling portion 214, 254, 234, 264. *See id.* The second tissue engaging device 240 comprises opposed articulable arms 230 with a tissue piercing element 250, 308, 356 disposed at a distal end of at least one said arm 230. *See id.* The articulable arms 230 are each configured for releasably engaging the interior of the hollow organ, with said second tissue engaging device 240 being movable relative to the first tissue engaging device 220 and hingedly pivotable relative to a long-axis of the elongated member 280, 290. *See id.* The proximal controlling portion of the elongated member 280, 290 is structured to actuate the tissue engaging devices 220, 240. *See id.*

2. Independent Claim 5

Independent claim 5 recites a tissue shaping instrument 200 comprising an elongated member 280, 290 having an inner tubular member 280 and an outer tubular member 290 concentrically disposed around the inner tubular member 280 and a proximal controlling portion 214, 254, 234, 264. *See, e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]); and FIGS. 25-29. The elongated member 280, 290 is of sufficient length to enable an operator to access an interior of a hollow organ of a subject with a distal portion of the elongated member 280, 290 while the proximal controlling portion 214, 254, 234, 264 remains outside of the subject. *See id.* A first tissue engaging device 220 is disposed on one of the inner and the outer tubular member 280, 290 and operably connected to the proximal controlling portion 214, 254, 234, 264. *See id.* The first tissue engaging device 220 is structured for releasably engaging at least the inner surface of the hollow organ.

A second tissue engaging device 240 is disposed on one of the inner and the outer tubular member 280, 290 and is operably connected to the proximal controlling portion 214, 254, 234, 264. *See id.* The second tissue engaging device 240 comprises opposed articulable arms 230 with a tissue piercing element 250, 308, 356 disposed at a distal end of at least one said arm 230. *See id.* The articulable arms 230 are each configured for (a) releasably engaging the interior of the hollow organ and for manipulating tissue thus engaged so as to reconfigure a portion of the interior of at least the interior of the hollow organ, (b) moving together relative to the first tissue

engaging device 220, and (c) working cooperatively with a tissue securing device 260, 270. *See id; see also* FIGS. 20 and 21. A tissue securing device 260, 270 is operably connected to the proximal controlling portion 214, 254, 234, 264, wherein the tissue securing device 260, 270 is effective for fixing tissue of the hollow organ in a reconfigured state, and wherein the proximal controlling portion 214, 254, 234, 264 of the instrument 200 is structured to actuate the tissue engaging devices 220, 240 and the tissue securing device 260, 270. *See id.*

3. Independent Claim 24

Independent claim 24 recites an apparatus comprising means for transorally engaging a plurality of regions of stomach tissue with a plurality of members 220, 240, 250 from within the stomach. *See, e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]); and FIGS. 25-29. At least one of the members 220, 240, 250 is configured to move toward another member 220, 240 250 to reconfigure tissue. *See id;* and FIGS. 22 and 23. The plurality of members 220, 240, 250 include a first member 220, 240 positioned on a central longitudinal axis and having a first securing part 210, 230 configured to engage a first stomach tissue section and a second member 220, 240 positioned on a central longitudinal axis and having a second securing part 210, 230 configured to engage a second stomach tissue section. *See id.* The first and second members 220, 240 are positioned on the same central longitudinal axis. *See id.* The means comprise an actuating mechanism 214, 254, 234, 264 operatively linking the first and second members 220, 240 to facilitate simultaneous independent movement of said members 220, 240 to draw together the first and second stomach tissue sections. *See id; see also* FIGS. 20 and 21. The apparatus further includes means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue. *See id.*

Claim 24 recites a means for transorally engaging a plurality of regions of stomach tissue with a plurality of members from within the stomach. The structure described in the specification as corresponding to the function of transorally engaging a plurality of regions of stomach tissue includes the cables 214, 254, 234, 264, the first and second members 220, 240, grasper 250, helical device 300, suction device 400, and equivalents thereof. These structures are described at p. 36, line 5 – p. 38, line 25 (paras. [0171]-[0175]); and FIGS. 25-29.

Claim 24 also recites a means comprising an actuating mechanism operatively linking the first and second members to facilitate simultaneous independent movement of said members.

The structure described in the specification as corresponding to the function of facilitating simultaneous independent movement of the first and second members includes the concentric inner and outer tubes 280, 290 coupled to hinged first and second members 220, 240, cables 214, 254, 234, 264, and equivalents thereof. These structures are described at p. 36, line 5 – p. 38, line 25 (paras. [0171]-[0175]); and FIGS. 25-29.

Claim 24 further recites means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue. The structure described in the specification as corresponding to the function of pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue includes graspers 250, helical spiral 304, suction-based tissue engaging device 400, and equivalents thereof. These structures are described at p. 36, line 5 – p. 38, line 25 (paras. [0171]-[0175]); and FIGS. 25-29.

4. Independent Claim 34

Independent claim 34 recites an apparatus 200 comprising a substantially rigid elongated member 280, 290 configured for transoral placement in the stomach. *See, e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]); and FIGS. 25-29. The apparatus 200 has a distal region including first and second movable members 220, 240 configured to be moved toward one another to reconfigure stomach tissue. *See id.* The first movable member 220, 240 is positioned on a central longitudinal axis and the second movable member 220, 240 is positioned on a central longitudinal axis. *See id.* The distal region being steerable as a unit, and means 260, 270 for deploying an implant from at least one of the members 220, 240 to secure the reconfigured tissue, wherein the first and second movable members 220, 240 are positioned on the same longitudinal central axis. *See id.*

Claim 34 recites a means for deploying an implant from at least one of the members to secure the reconfigured tissue. The structure described in the specification as corresponding to the function of deploying an implant from at least one of the members to secure the reconfigured tissue includes a staple actuating mechanism 264, 234, staple cartridge 260 and staple anvil 270, as well as comparable actuating mechanisms and end effectors to deliver a two part fastener 350, 360 as shown in FIG. 29, and equivalents thereof. These structures are described in the specification at p. 39, lines 11-25; (para. [0178]).

5. Dependent Claim 36

Dependent claim 36 recites that the elongated member 280, 290 includes a corkscrew element 300. *See e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]) and FIG. 27.

6. Independent Claim 53

Independent claim 53 recites an apparatus 200 comprising a plurality of tissue engaging members having at least a first member 220, 240 positioned on a central longitudinal axis and having a first securing part 210, 230 configured to engage a first stomach tissue section. *See, e.g.,* p. 36, line 5 – p. 38, line 4 (paras. [0171]-[0174]); p. 21, lines 9-16 (para. [0113]); and FIGS. 25-29. At least a second member 220, 240 is positioned on a central longitudinal axis and has a second securing part 210, 230 configured to engage a second stomach tissue section. *See id.* The first and second members 220, 240 are positioned on the same central longitudinal axis. An actuating mechanism 280, 290 operatively links the first and second members 220, 240 to facilitate simultaneous independent movement of the members 220, 240 to draw together first and second stomach tissue sections. *See id.* The apparatus 200 is configured for transorally engaging a plurality of regions of stomach tissue with the plurality of members from within the stomach and wherein at least one of the members 220, 240 is configured to move toward another member 240, 220 to reconfigure tissue. *See id.*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner improperly rejected claims 1-3, 45, and 49-51 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,395,367 of Wilk.

B. Whether the Examiner improperly rejected claims 24, 25, 27, 29-34, and 53 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,954,731 of Yoon.

C. Whether the Examiner improperly rejected claims 34, 35, 37, and 39-44 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,695,866 of Kuehn et al

D. Whether the Examiner improperly rejected claims 5-7, 9, 17, 18, and 20 pursuant to 35 U.S.C. §102(b) as being anticipated by, or in the alternative pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk.

E. Whether the Examiner improperly rejected claims 4, 10-13, and 21 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 5,289,963 of McGarry et al.

F. Whether the Examiner improperly rejected claims 8 and 52 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al.

G. Whether the Examiner improperly rejected claim 26 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,954,731 of Yoon in view of U.S. Patent No. 5,437,266 of McPherson et al.

H. Whether the Examiner improperly rejected claim 36 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al.

I. Whether the Examiner improperly rejected claim 14 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 6,695,866 of Kuehn et al.

J. Whether the Examiner improperly rejected claims 15 and 16 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 6,152,935 of Kammerer et al.

K. Whether the Examiner improperly rejected claim 19 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 5,954,731 of Yoon.

L. Whether the Examiner improperly rejected claims 28 and 38 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,954,731 of Yoon in view of U.S. Patent No. 5,395,367 of Wilk.

M. Whether the Examiner improperly rejected claim 46-48 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,395,367 of Wilk in view of U.S. Patent No. 5,350,391 of Iacovelli.

VII. ARGUMENT

A. Introduction

Appellants believe that each of the Examiner's numerous rejections is without basis, and respectfully request that they be reversed. Below Appellants address each of the rejections in the order in which they were put forth by the Examiner.

B. Rejection of Claims 1-3, 45, and 49-51 Pursuant to 35 U.S.C. §102b Over Wilk

1. The Examiner's Rejection

Claims 1-3, 45, and 49-51 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,395,367 of Wilk. With regard to independent claim 1, the Examiner states that Wilk discloses

> a tissue shaping instrument or apparatus including a proximal controlling portion at the vicinity of 118 structured to actuate the tissue engaging devices i.e., the controlling portion accommodates actuators for the devices, a distal effector portion at the vicinity of 116, an elongated member 114, and a first tissue engaging device e.g., 120 and a second tissue engaging device e.g., 122, where the second tissue engaging device is movable relative to the first tissue engaging device and hingedly pivotable relative to a long axis of the elongate member at the pivot point between 136a or 136b and 134 and/or between 136a and 138 or between 136b and 140, where the instrument is an endoscopic instrument, where the instrument includes a tissue securing device e.g., 126 or 130, where the instrument includes first and second actuating mechanisms e.g., 124 and 128, respectively.

Office Action dated October 19, 2009, pgs. 2-3. In his response to arguments, the Examiner goes on to argue that Wilk discloses a structure 136 that "enables tissue engaging members to be hingedly pivotable relative to the long-axis of the elongate member, where the pivotable connections provided by the structure are distinct from bending points of the shafts of the engaging members." *Id at 12.* The Examiner states that the term "hinge" is synonymous with the terms "pivot" and "joint" so that "bending of the grasping forceps results in turning, rotating, hinging, swinging, or pivoting of their shafts relative to the long axis" such that "the shafts 138, 140 are 'hingedly pivotable' relative to the long-axis." *Id.*

2. *The Scope and Content of Wilk*

Wilk is directed to a laparoscopic device that can have multiple laparoscopic instruments inserted into a rigid access sleeve to perform surgery as needed within a trocar or cannula. The Examiner refers to FIGS. 10-12c and col. 11, line 41 to col. 12, line 33 of Wilk as teaching the claimed device. This specified section and FIG. 11 of Wilk, which is reproduced herein, illustrate an embodiment in which two individual laparoscopic instruments 120 and 122 are inserted into a sleeve 114 such that each instrument 120, 122 exits the sleeve 114 on one end of the device while leaving its actuating mechanism 124, 128 on an opposite end of the device. The individual instruments 120, 122 each have a shaft 138, 140 with a grasping forceps 126, 130 disposed on a distal end thereof. The grasping forceps are connected to a push rod 134 by linkage arms 136a, 136b. The linkage arms 136a, 136b are "pivotably connected to shafts 138 and 140 of respective grasping forceps 120 and 122. Shafts 138 and 140 are flexible in a region immediately distal of frame member 114, thereby enabling relative spreading of grasping forceps 120 and 122 from a straightened or mutually parallel configuration..." *Wilk, col. 11, line 64 – col. 12, line 4, emphasis added.*

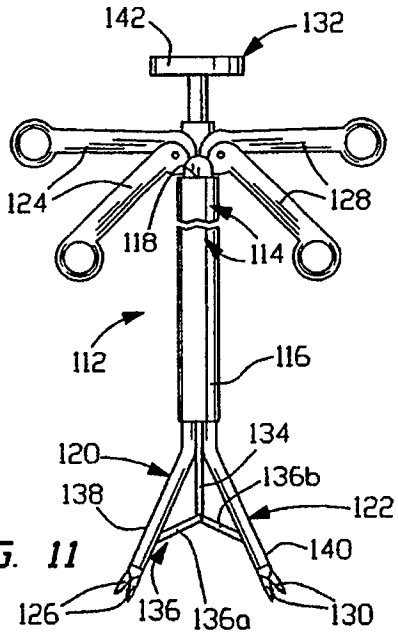


FIG. 11

3. *Wilk Does Not Identically Disclose the Recitations of Claim 1*

(a) Independent Claim 1

Independent claim 1 requires a tissue shaping instrument that includes an elongated member with two separate and distinct tissue engaging devices disposed thereon - a first tissue engaging device and a second tissue engaging device. The second tissue engaging device must be movable relative to the first tissue engaging device and hingedly pivotable relative to a long-axis of the elongate member.

To anticipate a claim, a single reference must disclose, expressly or inherently, all elements of the claim. "[E]ach and every element as set forth in the claim" must be found in the prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). For the reasons explained below, Wilk fails to disclose certain claim elements and features and thus it cannot be found to anticipate claim 1.

(b) Wilk Fails To Teach A Second Elongate Member That Is Hingedly Pivotable

At the outset, Appellants note that claim 1 requires that the second tissue engaging device be capable of movement in a very particular way. The second tissue engaging device must not only be pivotable relative to a long-axis of the elongate member, it must be "hingedly pivotable" relative to the long-axis. Claim 1 modifies the term "pivotable" with the term "hingedly" to indicate a particular structure that results in this very specific type of movement. The Examiner, however, argues that these two terms are equivalent. Thus, the Examiner would interpret claim 1 as requiring that the first tissue engaging device be "pivotably pivotable" or "hingedly hingable" relative to the long-axis of the elongate member. This complete misinterpretation not only ignores the claim language, it yields an absurd redundancy in the claim. The terms "hinge" and "pivot" have two distinct meanings, as is well recognized by a person of ordinary skill in the art. According to the Merriam-Webster Dictionary, the term "hinge" means "a jointed...device on which a door, lid, or other swinging part turns comprising typically a pair of metal leaves joined through the knuckles by a pin." *Merriam-Webster Dictionary, 1993, page 1071.* Similarly, the term "pivot" means "a real or apparent point or position on which something turns about, oscillates, or balances." *Id. at 1726.* The Examiner should give these terms their ordinary and customary meaning.

Wilk fails to teach or suggest a second tissue engaging device that is hingedly pivotable relative to the long-axis of the elongate member. The grasping forceps 120, 122 are not hingedly pivotable relative to the long axis of the device, as required by claim 1. Instead they are bendable relative to the long axis, not at any specific point, such as at a hinge, but at any point along their length. The shafts 138, 140 of the forceps 120, 122 are flexible components and are connected to the arms 136a, 136b. They bend outward in response to force applied by the arms 136a, 136b. Wilk teaches that the shafts 138, 140 of the grasping forceps 120, 122 are "flexible in a region immediately distal of a distal end of the frame member 114...thereby enabling a relative spreading of grasping forceps 120, 122 from a straightened...configuration...." *Wilk, col. 11, line 68 – col. 12, line 5.* The shafts 138, 140 are solid continuous members, making it impossible for them to be hinged or hingedly pivotable.

Furthermore, there is not a single mention in all of the Wilk reference of a "hinge" or of any other structure about which one portion of the device of Wilk could pivot relative to another portion. The only pivot points mentioned in Wilk are associated with the connections for the push rod 132 and the arms 136a, 136b. The Wilk passage to which the Examiner refers as teaching a hingedly pivotable tissue engaging device simply discloses that a push rod 132 is "pivotably" connected with arms 136a, 136b, and that the arms 136a, 136b are "pivotably" connected to grasping forceps 120, 122. The pivoted connections of the arms 136a, 136b and the push rod 132 have nothing to do with the shafts 138, 140 of the forceps 120, 122 even being pivotable, much less hingedly pivotable. Although the passage weakens the Examiner's argument, it does establish that Wilk understood the concept of a pivotable connection. Wilk thus refers to such a connection where it exists, such as where there is a pivot pin or hinge. Wilk does not characterize the shafts 138, 140 of the forceps 120, 122, as being pivotable simply because they are not.

Moreover, the Examiner relies on the figures, such as FIG. 11 which is reproduced above, to show a hingedly pivotable tissue engaging device. FIG. 11, however, simply shows that the shafts 138, 140 are bendable and that the arms 136a, 136b connect to the shafts 138, 140. There is no illustration of a structure on the shafts 138, 140 that could be interpreted as hingedly pivotable.

Accordingly, Wilk is deficient as a reference with regard to claim 1 because it fails to disclose a second tissue engaging device that is hingedly pivotable relative to the long-axis of the elongate member.

(c) Wilk Fails To Teach First and Second Tissue Engaging Devices Disposed on A Distal Effector Portion

Claim 1 also requires an elongated member having a distal effector portion and first and second tissue engaging devices disposed on the distal effector portion.

Wilk fails to teach or suggest two tissue engaging devices disposed on the same distal effector portion of an elongated member. Instead, Wilk discloses two separate and distinct "elongate devices" (i.e., shafts 138, 140), each having a single "tissue engaging device" (i.e., grasping forceps 120, 122) disposed at a distal end thereof. The two shafts 138, 140 are inserted through a frame member 114, which the Examiner refers to as the claimed elongated member. The Examiner further refers to the distal end 116 of the frame member 114 as the claimed distal effector portion. The grasping forceps 120, 122, however, are not disposed on the frame member 114 (or the distal end 116 of the frame member 114), but instead are disposed on the shafts 138, 140 that are separate from and pass through the frame member 114. The grasping forceps 120, 122 are not even physically close to the distal end 116 of the frame member 114, or any other portion of the frame member 114, and thus could never be considered as being "disposed on" the distal end 116 of the frame member 114.

Wilk is therefore deficient as an anticipatory reference for this additional, independent reason.

(d) Conclusion

For the reasons noted above, Wilk fails to disclose two claimed elements: (1) a second elongate member that is hingedly pivotable relative to a long-axis of the elongated member and (2) first and second tissue engaging devices disposed on a distal effector portion. Wilk is thus deficient as a reference and cannot anticipate claim 1. Accordingly, claim 1, as well as claims 2, 3, 45, and 49-51 which depend therefrom, distinguish over Wilk. Appellants respectfully request reversal of this rejection.

C. Rejection of Claims 24, 25, 27, and 29-33 Pursuant to 35 U.S.C. §102(e) Over Yoon

1. The Examiner's Rejection

Claims 24, 25, 27, and 29-33 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,954,731 of Yoon. The Examiner argues that Yoon discloses

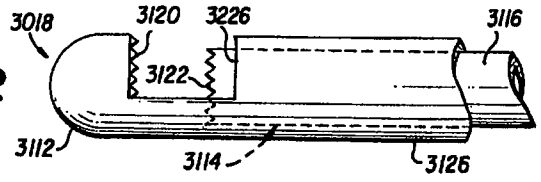
> an apparatus comprising means for engaging a plurality of stomach tissue regions with a plurality of members 3126, 3116 from within the stomach … where the plurality of members includes a first member having a first securing part 3120, a second member having a second securing part 3122, the means for engaging the including an actuating mechanism 14 operatively linking the first and second members to facilitate simultaneous independent movement of the members….

Office Action dated October 19, 2009, pg. 3.

2. The Scope and Content of Yoon

Yoon is directed to a surgical instrument having multiple rotatably mounted end effectors. One example of an end effector disclosed by Yoon is shown in FIG. 12, which is reproduced herein. The end effector includes a first jaw member 3112 in the form of an outer tubular sleeve with a cut-out or window 3226 having a grasping surface 3120 formed on a proximal-facing surface of the window 3226. The end effector also includes a second jaw member 3114 in the form of an inner tubular sleeve and having a grasping surface 3122 formed along a peripheral edge of the inner member to "operate cooperatively with the grasping surface at the distal end of the outer member to hold a suture needle or other objects within the window." *Yoon, col. 14, lines 65-67.*

FIG. 12



3. Yoon Does Not Identically Disclose the Recitations of Claim 24

(a) Independent Claim 24

Independent claim 24 recites, among other elements, an apparatus that includes a means for transorally engaging a plurality of regions of tissue with a plurality of members from within the stomach. The claim further requires that the plurality of members includes a first member and a second member positioned on the same longitudinal axis, and an actuating mechanism operatively linking the first and second members to facilitate simultaneous independent movement of the members to draw together first and second stomach tissue sections.

As noted above, to anticipate a claim, a single reference must disclose, expressly or inherently, all elements of the claim. "[E]ach and every element as set forth in the claim" must be found in the prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, with regard to the claim limitation pursuant to 35 U.S.C. §112, sixth paragraph reciting a means for transorally engaging a plurality of regions of tissue, the Federal Circuit has held that the "PTO [is] required by statute to look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *In re Donaldson*, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994). For the reasons explained below, Yoon fails to disclose certain claim elements and features and thus it cannot be found to anticipate claim 24.

(b) Yoon Fails to Disclose Simultaneous Independent Movement of the Members

Independent claim 24 requires that the means comprise an actuating mechanism linking the first and second members facilitate simultaneous independent movement of the members. The device of Yoon is not capable of such movement and so it lacks any such actuating mechanism. The two jaw members 3112, 3114 are operably connected to one another and thus will never be capable of simultaneous independent movement. If the first jaw member 3112 is moved by an actuating mechanism, the second jaw member 3114 will automatically move with the first jaw member 3112 because the two are attached. Even though the second jaw member 3112 presumably can be moved relative to the first jaw member 3114, the two jaw members 3112, 3114 must be capable of being moved independently simultaneously, and there must be a structure - an actuating mechanism – that makes such movement possible. Such a structure is simply not disclosed by Yoon.

Furthermore, when examining means plus function limitations, an Examiner must "look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *Id.* In this case, the recited "means comprising an actuating mechanism operatively linking the first and second members to facilitate simultaneous independent movement of said members" is described in Appellants' specification as concentric inner and outer tubes 280, 290 each hingedly coupled to one of a first and second member 220, 240. The inner and outer tubes 280, 290 can be moved independently, allowing the first and second members 220, 240 to be moved independently. Further, cables 214, 254, 234, 264 are independently coupled to the first and second members 220, 240. The cables 214, 254, 234, 264 can also be moved independently to cause independent movement of the first and second members 220, 240. In this way, the first member 220 can be moved completely independently of the second member 240 simultaneously with the second member 240 being moved independently of the first member 220. The device of Yoon, however, has no structure capable of allowing simultaneous independent movement of first and second members. The jaw members 3114, 3112 of Yoon are concentrically disposed around each other (rather than being coupled to concentrically disposed and independently movable tubes) and coupled together such that their movement is dependent. Further, they are not coupled to any cables or equivalent actuating mechanism structure that would allow them to each be moved independently simultaneously. Thus, Yoon does not disclose any device or structure that allows simultaneous independent movement of first and second members.

Yoon is therefore deficient as an anticipatory reference with regard to claim 24.

(c) Yoon Fails to Disclose Transoral Tissue Engagement

Independent claim 24 also requires a means for transorally engaging a plurality of regions of stomach tissue from within the stomach. There is no teaching or suggestion in Yoon that its device is capable of transorally engaging regions of stomach tissue. The device of Yoon is a rigid device, having no joints, with a fixed length that is intended to be used in endoscopic and laproscopic procedures in which the device is inserted through "puncture sites...of an anatomical cavity using penetrating instruments including an obturator, such a trocar, disposed within a portal sleeve." *Yoon, col. 1, lines 14-18; see also col. 4, lines 15-20.* The strict rigidity and short

length of the device of Yoon, both of which attributes are explained by Yoon, renders the Yoon device suitable for inserting through a portal sleeve and into a puncture site in a cavity wall. However, these design features make the Yoon device impossible to use for transorally engaging regions of stomach tissue. The device is simply not physically long enough to be introduced into the stomach cavity transorally, and its lack of jointed portions (or of any flexible portion) render the device unable to be used in such a way.

Furthermore, as noted above, when examining means plus function limitations, an Examiner must "look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *Id.* In this case, the recited "means for transorally engaging a plurality of regions of stomach tissue from within the stomach" is described in Appellants' specification as a jointed device having a length that is suitable for being introduced into the stomach transorally. Yoon does not disclose any such device, nor any equivalent device, that has a length suitable for being introduced into the stomach transorally.

For all of these reasons, Yoon is deficient as an anticipatory reference with regard to claim 24.

(d) Yoon Fails to Disclose Engaging a Plurality of Regions of Stomach Tissue

Claim 24 requires a means for engaging a plurality of regions of stomach tissue with a plurality of members. The device of Yoon is not suitable for engaging a plurality of regions of tissue. As explained by the Examiner in support of his rejection, there are only two engaging surfaces 3120, 3122 on the device of Yoon that come together to grasp something therebetween, effectively forming a device with only a single functionality. At most, the device of Yoon could engage a single region of tissue between the jaws 3112, 3114, but the device is not physically capable of engaging more than one region of tissue because the first region of tissue would be released from the jaws upon attempting to grasp a second region of tissue.

Furthermore, the device of Yoon is not even suitable for engaging stomach tissue. Yoon teaches that the grasping surfaces 3120 and 3122 are intended to hold a "suture needle or other

objects within the window." *Yoon, col. 14, lines 66-67.* These jaw members are therefore not intended to grasp tissue at all, and the recessed window 3226 and recessed grasping surface 3122 would make it impossible for them to engage any portion of stomach tissue. That is, the window and jaws 3112, 3114 would be recessed relative to the wall of the stomach. The walls of the stomach are smooth and flat, and the linear jaws 3112, 3114 of Yoon are not capable of "reaching out" to grasp smooth, flat tissue. The device is therefore not capable of engaging stomach tissue as required by claim 24.

Finally, as noted above, when examining means plus function limitations, an Examiner must "look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *Id.* In this case, the recited "means for engaging a plurality of regions of stomach tissue" is described in Appellants' specification as cables 214, 254, 234, 264 linking the first and second members 220, 240 and maneuvering the first and second members 220, 240 individually to engage a plurality of regions of stomach tissue. The device of Yoon does not disclose any such mechanism. The grasping surfaces 3120, 3122 are coupled together one inside the other and cannot be maneuvered individually to grasp more than one region of tissue, if any. There is no disclosure of any cables or equivalent mechanism that would be capable of linking and maneuvering the jaws 3112, 3114 of Yoon individually to engage a plurality of regions of stomach tissue.

For all of these reasons, Yoon is deficient as an anticipatory reference.

(e) Conclusion

At noted above, Yoon fails to disclose (1) simultaneous independent movement of the members, (2) transoral tissue engagement, and (3) a means for engaging a plurality of regions of stomach tissue. Yoon is thus deficient as a reference and cannot anticipate claim 24. Accordingly, claim 24, as well as claims 25, 27, and 29-33 which depend therefrom, distinguish over Yoon. Appellants respectfully request reversal of this rejection.

D. Rejection of Claim 34 Pursuant to 35 U.S.C. §102(e) Over Yoon

1. The Examiner's Rejection

Claim 34 is rejected pursuant to 35 U.S.C. §102(e) as being anticipated by Yoon. The Examiner addresses this rejection in combination with the rejection of claim 24, and does not give further rationale specific to this claim.

2. Yoon Does Not Identically Disclose the Recitations of Claim 34

(a) Independent Claim 34

Independent claim 34 recites, among other elements, an apparatus comprising a substantially rigid elongated member configured for transoral placement in the stomach and having first and second movable members and a means for deploying an implant from at least one of the members to secure reconfigured tissue.

As noted above, to anticipate a claim, a single reference must disclose, expressly or inherently, all elements of the claim. "[E]ach and every element as set forth in the claim" must be found in the prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, with regard to the recited "means for deploying an implant," the "PTO [is] required by statute to look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *In re Donaldson*, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994). For the reasons explained below, Yoon fails to disclose certain claim elements and features and thus it cannot be found to anticipate claim 34.

(b) Yoon Fails to Disclose Means For Deploying An Implant From At Least One of the Members

Independent claim 34 requires a means for deploying an implant from one of the first and second movable members. There is no teaching or suggestion in Yoon that the jaw members 3112 and 3114 are capable of deploying an implant therefrom. The jaw members 3112 and 3114 have grasping surfaces that are merely intended to hold a tool and have no "means for deploying an implant" as required by claim 34. When the jaw members 3112 and 3114 close to grasp an object, they are not capable of deploying an implant therefrom simply because they are only configured to open and close on the tool they are intended to grasp.

Furthermore, as noted above, when examining means plus function limitations, an Examiner must "look to [Appellants'] specification and construe the 'means' language...as limited to the corresponding structure disclosed in the specification and equivalents thereof." *Id.* In this case, the recited "means for deploying an implant from one of the first and second movable members" is described in Appellants' specification as either a staple cartridge 260 and stapler anvil 270, a comparable device for delivering a two part fastener 350, 360 illustrated in FIG. 29, and equivalents thereof. The device of Yoon clearly does not have any one of a stapler cartridge and anvil, a comparable device for delivering a two-part fastener, or any other equivalent fastener delivery mechanism. The jaw members 3112 and 3114 are simple grasping devices and have no capability to deploy an implant therefrom. Yoon is clearly deficient as a reference with regard to this requirement of claim 34.

(c) Yoon Fails to Disclose an Elongated Member Configured for Transoral Placement in the Stomach

Independent claim 34 also requires an elongated member configured for transoral placement in the stomach. There is no teaching or suggestion in Yoon that its device is capable of transoral placement in the stomach. The device of Yoon has no jointed portions that would allow it to be maneuvered transorally, and has a fixed length that is intended to be used in endoscopic and laproscopic procedures in which the device is inserted through "puncture sites...of an anatomical cavity using penetrating instruments including an obturator, such a trocar, disposed within a portal sleeve." *Yoon, col. 1, lines 14-18; see also col. 4, lines 15-20.* The lack of any joints and the short length of the device of Yoon, both of which attributes are explained by Yoon, renders the Yoon device suitable for inserting through a portal sleeve and into a puncture site in a cavity wall. However, these design features make the Yoon device impossible to use for transoral placement in the stomach. The device is simply not physically long enough to be introduced into the stomach cavity transorally, and its lack of jointed portions (or of any pivotable portion) render the device unable to be used in such a way.

(d) Conclusion

At noted above, Yoon fails to disclose at least two claim elements: (1) a means for deploying an implant from at least one of the members and (2) transoral placement in the

stomach. Yoon is thus deficient as a reference and cannot anticipate claim 34. Accordingly, claim 34 distinguishes over Yoon. Appellants respectfully request reversal of this rejection.

E. Rejection of Claim 53 pursuant to 35 U.S.C. §102(e) Over Yoon

1. The Examiner's Rejection

Claim 53 is rejected pursuant to 35 U.S.C. §102(e) as being anticipated by Yoon. The Examiner addresses this rejection in combination with the rejection over claim 24, and does not give further rationale specific to this claim.

2. Yoon Does Not Identically Disclose the Recitations of Claim 53

(a) Independent Claim 53

Independent claim 53 recites, among other elements, an apparatus comprising an actuating mechanism operatively linking first and second members to facilitate simultaneous independent movement of the members to draw together first and second stomach tissue sections, wherein the apparatus is configured for transorally engaging a plurality of regions of stomach tissue with the plurality of members from within the stomach.

As noted above, to anticipate a claim, a single reference must disclose, expressly or inherently, all elements of the claim. "[E]ach and every element as set forth in the claim" must be found in the prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). For the reasons explained below, Yoon fails to disclose certain claim elements and features and thus it cannot be found to anticipate claim 53.

(b) Yoon Fails to Disclose Simultaneous Independent Movement of the Members

Independent claim 53 requires that an actuating mechanism link the first and second members to facilitate simultaneous independent movement of the members. As noted above with respect to claim 24, the device of Yoon is not capable of such movement and so it lacks any such actuating mechanism. The two jaw members 3112, 3114 are operably connected to one another and thus will never be capable of simultaneous independent movement. If the first jaw member 3112 is moved by an actuating mechanism, the second jaw member 3114 will

automatically move with the first jaw member 3112 because the two are attached. Even though the second jaw member 3112 presumably can be moved relative to the first jaw member 3114, the two jaw members 3112, 3114 must be capable of being moved independently simultaneously, and there must be a structure - an actuating mechanism – that makes such movement possible. Such a structure is simply not disclosed by Yoon.

Yoon plainly lacks any actuating mechanism that links the first and second members, making it possible for the members to move independently at the same time. Although part of claim 53 includes functional recitations, "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." MPEP, § 2173g. The jaw members 3114, 3112 of Yoon are not capable of simultaneous independent movement and thus Yoon is deficient as an anticipatory reference with regard to claim 53.

(c) Yoon Fails to Disclose Transoral Tissue Engagement

Independent claim 53 also requires an apparatus configured for transorally engaging a plurality of regions of stomach tissue from within the stomach. There is no teaching or suggestion in Yoon that its device is capable of transorally engaging regions of stomach tissue. The device of Yoon is a rigid device, having no joints, with a fixed length that is intended to be used in endoscopic and laproscopic procedures in which the device is inserted through "puncture sites...of an anatomical cavity using penetrating instruments including an obturator, such a trocar, disposed within a portal sleeve." *Yoon, col. 1, lines 14-18; see also col. 4, lines 15-20.* The strict rigidity and short length of the device of Yoon, both of which attributes are explained by Yoon, renders the Yoon device suitable for inserting through a portal sleeve and into a puncture site in a cavity wall. However, these design features make the Yoon device impossible to use for transorally engaging regions of stomach tissue. The device is simply not physically long enough to be introduced into the stomach cavity transorally, and its lack of jointed portions (or of any flexible portion) render the device unable to be used in such a way. Yoon is therefore deficient as an anticipatory reference for this additional reason.

(d) Yoon Fails to Disclose Engaging a Plurality of Regions of Stomach Tissue

Claim 53 requires an apparatus configured for engaging a plurality of regions of stomach tissue with a plurality of members. The device of Yoon is not suitable for engaging a plurality of regions of tissue. There are only two engaging surfaces 3120, 3122 on the device of Yoon that come together to grasp something therebetween effectively forming a device with only a single functionality. At most, the device of Yoon could engage a single region of tissue between the jaws 3112, 3114, but the device is not physically capable of engaging more than one region of tissue because the first region of tissue would be released from the jaws upon attempting to grasp a second region of tissue.

Furthermore, the device of Yoon is not even suitable for engaging stomach tissue. Yoon teaches that the grasping surfaces 3120 and 3122 are intended to hold a "suture needle or other objects within the window." *Yoon, col. 14, lines 66-67.* These jaw members are therefore not intended to grasp tissue at all, and the recessed window 3226 and recessed grasping surface 3122 would make it impossible for them to engage any portion of stomach tissue. That is, the window 3226 and jaws 3112, 3114 would be recessed relative to the wall of the stomach. The walls of the stomach are smooth and flat, and the linear jaws 3112, 3114 of Yoon are not capable of "reaching out" to grasp smooth, flat tissue. The device is therefore not capable of engaging stomach tissue as required by claim 53.

For both of these reasons, Yoon is deficient as an anticipatory reference.

(e) Conclusion

At noted above, Yoon fails to disclose at least three claim elements: (1) simultaneous independent movement of the members, (2) transoral tissue engagement, and (3) a means for engaging a plurality of regions of stomach tissue. Yoon is thus deficient as a reference and cannot anticipate claim 53. Accordingly, claim 53 distinguishes over Yoon. Appellants respectfully request reversal of this rejection.

F. Rejection of Claims 34, 35, 37, and 39-44 Pursuant to 35 U.S.C. §102(e) Over Kuehn

1. The Examiner's Rejection

Claims 34, 35, 37, and 39-44 are rejected pursuant to 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,695,866 of Kuehn. The Examiner argues that Kuehn discloses

> an apparatus comprising a substantially rigid i.e., somewhat flexible elongated member 108 configured for transoral placement in the stomach, where the elongated member having a steerable distal region including first and second movable members Jaws of 404: 428, 430 configured to be moved toward one another...where the first and second movable members are positioned on the same longitudinal axis.

Office Action dated October 19, 2009, page 4.

2. The Scope and Content of Kuehn

Kuehn et al. ("Kuehn") is directed to a device used for mitral and tricuspid valve repair as illustrated in FIGS. 17 and 19A, which are reproduced herein. The device is attached to a

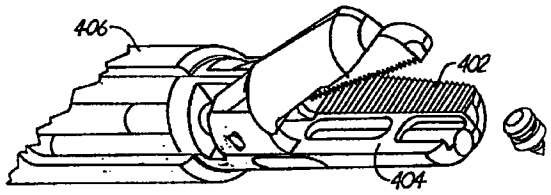


Fig. 17

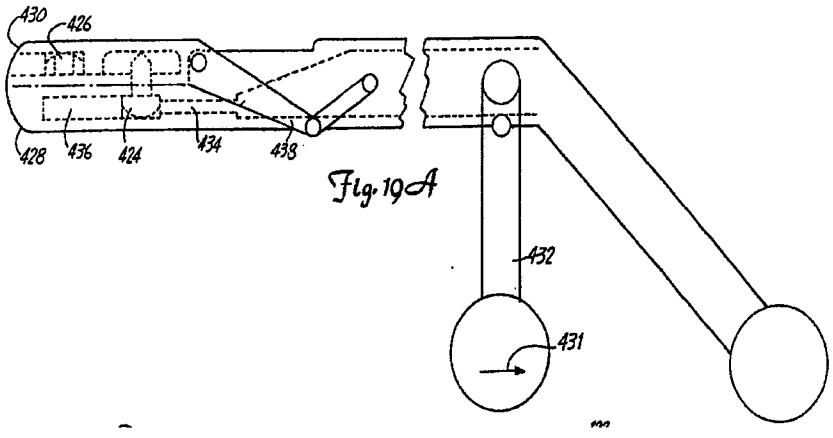


Fig. 19A

tubular shaft 406 that is "preferably flexible so that it can be guided through the body to the desired location" within the heart. *Kuehn, col. 6, lines 30-33.* The shaft 406 includes a distal fastener applicator 404 for applying a fastener to heart valve leaflets for valve repair. Fastener applicator 404 holds tack 424 and cap 426 in separate housings for deployment. When jaw 430 is opened by the movement of the lever 432, rod 434 slides tack 424 within track 436 to a position aligning cap 426 with tack 424. Jaw 428 remains stationary because it is not pivotally attached to the elongate member. When jaw 430 is subsequently closed, tack 424 engages cap 426, thereby fastening the leaflets.

3. Kuehn Does Not Identically Disclose the Recitations of Claim 34

(a) Independent Claim 34

Independent claim 34 recites, among other elements, an apparatus comprising a substantially rigid elongated member configured for transoral placement in the stomach and having a distal region with first and second movable members configured to be moved toward one another to reconfigure stomach tissue.

As noted above, to anticipate a claim, a single reference must disclose, expressly or inherently, all elements of the claim. "[E]ach and every element as set forth in the claim" must be found in the prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). For the reasons explained below, Kuehn fails to disclose certain claim elements and features and thus it cannot be found to anticipate claim 34.

(b) Kuehn Fails to Disclose First and Second Movable Members

Claim 34 requires first and second movable members, each configured to be moved toward one another. Kuehn fails to meet this requirement because Kuehn fails to teach or suggest two members, each of which is moveable and capable of movement toward one another. As shown in FIG. 19A of Kuehn above, only the jaw 430 is capable of opening and closing relative to the fixed jaw 428. The jaw 430 is pivotally attached to the elongate member such that it can be opened and closed by the lever 432. The jaw 428, however, is not pivotally attached to the elongate member; instead it is rigidly attached thereto and/or integrally formed therewith. The jaw 428 is not capable of any movement whatsoever and it is therefore not movable toward the jaw 430 as required by claim 34.

Accordingly, Kuehn completely lacks an element required by claim 34. Kuehn lacks two members which are both movable and capable of movement toward one another. Kuehn is therefore deficient with regard to claim 34.

(c) Kuehn Fails to Disclose a Substantially Rigid Elongated Member

Claim 34 also requires a substantially rigid elongated member. With regard to this requirement, the Examiner states that the phrase "substantially rigid" means "somewhat flexible." Appellants strongly disagree with this characterization. A substantially rigid

elongated member is not "somewhat flexible." It is the opposite of flexible, and it is improper for the Examiner to characterize it as such.

Furthermore, the device of Kuehn is not substantially rigid. Kuehn teaches that its device is "preferably flexible so that it can be guided through the body to the desired location." *Kuehn, col. 6, lines 31-33, emphasis added.* This teaching of Kuehn is the exact opposite of what is required by claim 34. The device of Kuehn is not even "somewhat flexible;" it is fully flexible so that it can be guided through a patient's vascular system, specifically to reach the heart. A "substantially rigid" device would clearly not be suitable for such an application. This is a further deficiency of Kuehn with regard to claim 34.

(d) Conclusion

At noted above, Kuehn fails to disclose at least two claim elements: (1) first and second movable members and (2) a substantially rigid elongated member. Kuehn is thus deficient as a reference and cannot anticipate claim 34. Accordingly, claim 34, as well as claims 35, 37, and 39-44 distinguish over Kuehn. Appellants respectfully request that the rejection of claim 34 be reversed.

G. Rejection of Claims 5-7, 9, 17, 18, and 20 Pursuant to 35 U.S.C. §102(b) or §103(a) Over Wilk

1. The Examiner's Rejection

Claims 5-7, 9, 17, 18, and 20 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by Wilk, or in the alternative, pursuant to 35 U.S.C. §103(a) as being obvious over Wilk. In the rejection and in the Response to Arguments of the Office Action dated October 19, 2009, the Examiner suggests multiple interpretations as to how Wilk meets the requirements of claim 5. If these interpretations are examined together, however, it becomes clear that Wilk cannot actually meet all of the requirements of claim 5. Appellants

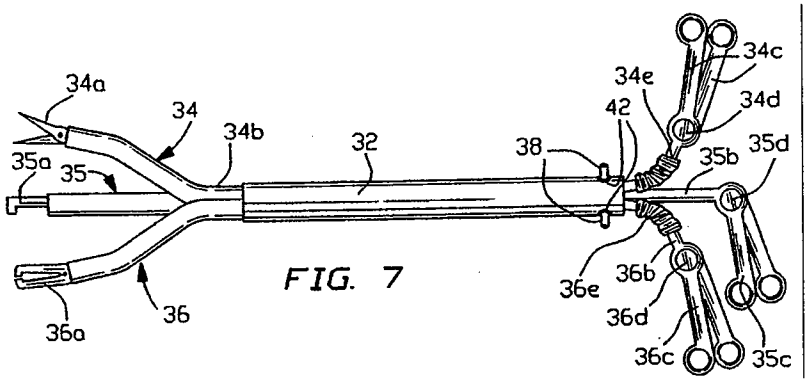


FIG. 7

therefore explain these interpretations and their failures below.

2. The Scope and Content of Wilk

In one embodiment of Wilk shown in FIG. 7, which is reproduced above, Wilk discloses an instrument with a rigid sleeve 32 and three instruments 34, 35, 36 that are inserted inside the sleeve. Each instrument 34, 35, 36 includes an operative tip 34a, 35a, 36a at a distal end of a central shaft 34b, 35b, 36b.

3. Wilk Does Not Disclose the Recitations of Claim 5

(a) Independent Claim 5

Independent claim 5 requires a tissue shaping instrument that requires, among other elements, an elongated member having a inner tubular member and an outer tubular member concentrically disposed around the inner tubular member, a first tissue engaging device disposed on one of the inner and the outer tubular member, and a second tissue engaging device disposed on one of the inner and the outer tubular member.

(b) The Examiner's First Interpretation Pursuant to 35 U.S.C. § 102b

In a first interpretation, the Examiner asserts that Wilk teaches "an elongated member having an inner tubular member (e.g., sheath of 35 or 36) and an outer tubular member 32 concentrically disposed around the inner tubular member." *Office Action dated October 19, 2009, page 5.* Regarding this rejection, in his Response to Arguments, the Examiner provides the definition of "concentric" and argues that he is giving the term its "broadest reasonable interpretation."

The first definition of concentric that the Examiner puts forth is: "with common middle point: describes circles and spheres of different sizes with the same middle point." The second definition is: "with common axis: with common axis or center line." *Id. at 12.* The Examiner uses FIG. 7 of Wilk to illustrate what he views as the "broadest reasonable interpretation" of Wilk. With regard to the first definition, the Examiner states that "the sheaths of elements 34, 35, and 36 can be said to share a common middle point with element 32. That is, a middle point between the axes of the sheaths (inner tubular member) is common with the axis of element 32

(outer tubular member)." *Id., page 12.* This is simply wrong. Each of the three circular shafts 34, 35, and 36 have their own middle point that is different from one another and offset from the middle point of the sheath 32. The middle points of the shafts 34, 35, and 36 are not common with the middle point of the sheath 32, as the definition requires. The Examiner's statement that "a middle point between the axes is common with the axis of element 32" has nothing to do with the definition of "concentric." Indeed the middle point of the sheath 32 will not be in the middle point of any of the shafts 34, 35, 36 – it will be outside of these shafts. Thus, the three shafts 34, 35, 36 extending through the sheath 32 cannot meet the requirement that the outer tubular member be disposed concentrically around the inner tubular member.

(c) The Examiner's Second Interpretation Pursuant to 35 U.S.C. § 102(b)

With regard to the second definition of "concentric "and under the Examiner's second interpretation, the Examiner asserts that "element 144 (outer tubular member in this case) can be said to have a common axis with element 32 (the inner tubular member in this case)." *Id. at 13.* This too is plainly wrong. First, element 144 in FIG. 12A is never taught by Wilk as being usable with sheath 32. Regardless, even if they are used together in the way the Examiner suggests, neither the element 144 nor the sheath 32 has a tissue engaging device disposed thereon, as also required by claim 5. In particular, claim 5 requires that the first and second tissue engaging devices be disposed on one of the inner and the outer tubular member. The shafts 34, 35, and 36 could never be disposed on either the element 144 or the sheath 32 because they must be capable of moving freely within and through the sheath 32, as explained in more detail below. Accordingly, under this second interpretation, Wilk still cannot meet all of the requirements of claim 5.

With regard to another aspect of claim 5, the Examiner argues that the shafts 34, 35, and 36 are in contact with one another and thus meet the requirement of claim 5 that the first and second tissue engaging devices be disposed on the inner tubular member. Although the Examiner's argument it is not clear, Appellants believe the Examiner is saying that any of the shafts 34, 35, and 36 can be the claimed inner tube and any of the other shafts can be a tissue engaging device "disposed on" the inner tube because they contact one another. Although Appellants disagree with this interpretation of "disposed on," Wilk still cannot meet the other

requirements of the claim. In particular, under this interpretation, the outer tube sheath 32 is not disposed concentrically around the inner tube i.e., one of the shafts 34, 35, 36 for all of the reasons noted above.

(d) The Examiner's Third Interpretation Pursuant to 35 U.S.C. § 103(a)

Finally, in an alternate rejection of claim 5 pursuant to 35 U.S.C. §103(a), the Examiner appears to admit that the only configuration of Wilk that meets the "concentric" requirement of claim 5 is the device of FIG. 4 and/or of FIGS. 12A-12C in which the tissue manipulation instrument is placed through a cannula or other outer tube. The Examiner then admits that these devices do not have tissue engaging devices disposed on one of the inner and the outer tube. But the Examiner says it would be obvious "to dispose the first and second tissue engaging devices on the proximal surface of one of the inner tubular member and the outer tubular member. Such a configuration would safely prevent the engaging devices from being inserted too far or dropped through a tubular member, and it would allow the actuators of the engaging devices to remain outside of a patient's body for convenient access to the devices by a user." *Office Action dated May 11, 2009, page 7.*

Appellants strongly disagree that this proposed modification would have been obvious to one skilled in the art, as it would completely destroy the purpose and function of the device of Wilk. The Background of Wilk explains the problem it is attempting to solve. Wilk states that "[i]t frequently occurs during laparoscopic surgery that an additional instrument is temporarily required. Inserting this extra instrument has usually involved either temporarily removing one of the other instruments or forming another perforation with a trocar." *Wilk, col. 1, lines 62-66.* Wilk then discloses a device in which multiple tubular members can be inserted through a sleeve for ease of manipulation and adjustment. It teaches that the tubular members are designed to be slidably disposed within the sleeve to move between retracted and extended positions and that the instruments are intended to be selectively replaced with different actuators as needed. In fact, Wilk states that the "handles are preferably locked in some way to the instrument shafts" for easier replacement. *Wilk, col. 3, lines 5-40.* Modifying Wilk to dispose the proximal portions of the instruments (i.e., the handles) on the proximal portion of the inner or outer tube would completely remove the ability of the instruments to be slidable relative to the sheath and to be

selectively replaced as needed. This is the fundamental solution to the problem Wilk was attempting to solve, and the Examiner's proposed modification would destroy the solution.

In addition, the reasoning that the Examiner gives for such a modification is also faulty. The Examiner claims that the modification would essentially prevent the instruments from being inserted too far or from being dropped through the tubular member. A simple glance at any of the figures of Wilk, however, clearly shows that the handle portions of the instruments have been designed to be much too large to "drop" through the sheath or cannula even in a vertical orientation. It would be impossible for them to do so. Furthermore, the fact that the handles of the instruments have additionally been designed to be used in an angular or horizontal orientation relative to the tubular member illustrates the further impossibility of such an occurrence. The Examiner's proposed modification of Wilk simply would not have been obvious to one skilled in the art.

For all of these many reasons, claim 5, as well as claims 6, 7, 9, 17, 18, and 20 which depend therefrom, distinguish over Wilk. Appellants respectfully request that the rejection of claim 5 be reversed.

H. Rejection of Claims 4, 10-13, and 21 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of McGarry

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claims 4, 10-13, and 21 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,289,963 of McGarry et al. ("McGarry"). Wilk fails to teach or suggest the requirements of independent claims 1 and 5, from which claims 4, 10-13, and 21 depend. McGarry is directed to a surgical stapler and does not remedy the deficiencies of Wilk with regard to claims 1 and 5, which are noted in detail above. Accordingly, claims 4, 10-13, and 21 distinguish over Wilk in view of McGarry at least because they depend from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

I. Rejection of Claims 8 and 52 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of McPherson

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claims 8 and 52 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al. ("McPherson"). Wilk fails to teach or suggest the requirements of independent claims 1 and 5, from which claims 8 and 52 depend, for the reasons noted above. McPherson is directed to a coil screw retractor and does not remedy the deficiencies of Wilk with regard to claims 1 and 5. Accordingly, claims 8 and 52 distinguish over Wilk in view of McPherson at least because they depend from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

J. Rejection of Claim 26 Pursuant to 35 U.S.C. § 103(a) Over Yoon in View of McPherson

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claim 26 pursuant to 35 U.S.C. § 103(a) as being obvious over Yoon in view of McPherson. Yoon fails to teach or suggest the requirements of independent claim 24, from which claim 26 depends, for the reasons noted above. McPherson is directed to a coil screw retractor and does not remedy the deficiencies of Yoon with regard to claim 24. Accordingly, claim 26 distinguishes over Yoon in view of McPherson at least because it depends from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

K. Rejection of Claim 36 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of McPherson

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claim 36 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al. ("McPherson"). The Examiner argues that Wilk discloses the invention substantially as claimed, but fails to disclose a corkscrew like element as required by claim 36. The Examiner therefore relies on McPherson to remedy the deficiency of Wilk. Claim 34, from which claim 36 depends, however is not rejected over Wilk and thus distinguishes over Wilk. Accordingly, claim 36 distinguishes over Wilk in view of McPherson at least because it depends from a claim distinguishable over Wilk in view of McPherson. Appellants respectfully request that the rejection of claim 36 be reversed.

L. Rejection of Claim 14 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of Kuehn

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claim 14 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of Kuehn. Wilk fails to teach or suggest the requirements of independent claim 5, from which claim 14 depends, for the reasons noted above. Kuehn is directed to a device for mitral valve repair and does not remedy the deficiencies of Wilk with regard to claim 5. Accordingly, claim 14 distinguishes over Wilk in view of Kuehn at least because it depends from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

M. Rejection of Claims 15 and 16 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of Kammerer

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claims 15 and 16 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of U.S. Patent No. 6,152,935 of Kammerer et al ("Kammerer"). Wilk fails to teach or suggest the requirements of independent claim 5, from which claims 15 and 16 depend, for the reasons noted above. Kammerer is directed to H-shaped tissue fastener and does not remedy the deficiencies of Wilk with regard to claim 5. Accordingly, claims 15 and 16 distinguish over Wilk in view of Kammerer at least because they depend from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

N. Rejection of Claim 19 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of Yoon

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claim 19 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of Yoon. Wilk fails to teach or suggest the requirements of independent claim 5, from which claim 19 depends, for the reasons noted above. Yoon is directed to an endoscopic surgical instrument and does not remedy the deficiencies of Wilk with regard to claim 19. Accordingly, claim 26 distinguishes over Wilk in view of Yoon at least because it depends from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

O. Rejection of Claims 28 and 38 Pursuant to 35 U.S.C. § 103(a) Over Yoon in View of Wilk

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claims 28 and 38 pursuant to 35 U.S.C. § 103(a) as being obvious over Yoon in view of Wilk. Yoon fails to teach or suggest the requirements of independent claims 24 and 34, from which claims 28 and 38 depend, for the reasons noted above. Wilk is directed to a laparoscopic surgical instrument and does not remedy the deficiencies of Yoon with regard to claims 24 and 34. Accordingly, claims 28 and 38 distinguish over Yoon in view of Wilk at least because they depend from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

P. Rejection of Claims 46-48 Pursuant to 35 U.S.C. § 103(a) Over Wilk in View of Iacovelli

1. The Examiner's Rejection and Appellants Response

The Examiner rejects claims 46-48 pursuant to 35 U.S.C. § 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,350,391 of Iacovelli. Wilk fails to teach or suggest the requirements of independent claim 1, from which claims 46-48 depend, for the reasons noted above. Iacovelli is directed to a laparoscopic surgical instrument and does not remedy the deficiencies of Wilk with regard to claim 1. Accordingly, claims 46-48 distinguish over Wilk in view of Iacovelli at least because they depend from an allowable base claim. Appellants respectfully request withdrawal of the rejection.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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APPENDIX A: CLAIMS ON APPEAL

1. (Previously Presented) A tissue shaping instrument, comprising:

an elongated member having a distal effector portion and a proximal controlling portion, the elongated member being of sufficient length to enable an operator to access an interior of a hollow organ of a subject with the distal effector portion while the proximal controlling portion remains outside of the subject;

a first tissue engaging device disposed on the distal effector portion of the elongated member and operably connected to the proximal controlling portion, the first tissue engaging device being structured for releasably engaging at least the inner surface of the hollow organ; and

a second tissue engaging device also disposed on the distal effector portion of the elongated member and operably connected to the proximal controlling portion, the second tissue engaging device comprising opposed articulable arms with a tissue piercing element disposed at a distal end of at least one said arm, said articulable arms each configured for releasably engaging the interior of the hollow organ, with said second tissue engaging device being movable relative to the first tissue engaging device and hingedly pivotable relative to a long-axis of the elongated member,

wherein the proximal controlling portion of the elongated member is structured to actuate the tissue engaging devices.

2. (Original) The tissue shaping instrument of claim 1, wherein the instrument is an endoscopic instrument.

3. (Previously Presented) The tissue shaping instrument of claim 1, further comprising a tissue securing device disposed at the distal effector portion and operably connected to the proximal controlling portion.

4. (Original) The tissue shaping instrument of claim 3, wherein at least one tissue fixation device is configured to be loaded into the tissue securing device by a person using the device.

5. (Previously Presented) A tissue shaping instrument, comprising:

an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and a proximal controlling portion, the elongated member being of sufficient length to enable an operator to access an interior of a hollow organ of a subject with a distal portion of the elongated member while the proximal controlling portion remains outside of the subject;

a first tissue engaging device disposed on one of the inner and the outer tubular member and operably connected to the proximal controlling portion, the first tissue engaging device being structured for releasably engaging at least the inner surface of the hollow organ;

a second tissue engaging device disposed on one of the inner and the outer tubular member and operably connected to the proximal controlling portion, the second tissue engaging device comprising opposed articulable arms with a tissue piercing element disposed at a distal end of at least one said arm, said articulable arms each configured for

a releasably engaging the interior of the hollow organ and for manipulating tissue thus engaged so as to reconfigure a portion of the interior of at least the interior of the hollow organ,

b moving together relative to the first tissue engaging device, and

c working cooperatively with a tissue securing device; and

a tissue securing device operably connected to the proximal controlling portion, wherein the tissue securing device is effective for fixing tissue of the hollow organ in a reconfigured state;

wherein the proximal controlling portion of the instrument is structured to actuate the tissue engaging devices and the tissue securing device.

6. (Original) The instrument of claim 5 wherein the instrument is an endoscopic instrument.

7. (Original) The tissue shaping instrument of claim 5 wherein either or both the first tissue engaging device and the second tissue engaging device comprises a jawed clamp.

8. (Original) The tissue shaping instrument of claim 5 wherein at least one of the first tissue engaging device and the second tissue engaging device comprises a corkscrew-like retractor.

9. (Original) The tissue shaping instrument of claim 5 wherein the tissue securing device

comprises a stapler.

10. (Original) The tissue shaping instrument of claim 9 wherein the stapler comprises a one-sided stapler.

11. (Original) The tissue shaping instrument of claim 5 wherein the tissue securing device comprises a device structured for delivering at least one biocompatible tissue fixation device into a tissue.

12. (Original) The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is selected from the group consisting of a staple, a clip, a tack, a rivet, a two-part fastener, a helical fastener, a suture, and a T-bar suture.

13. (Original) The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a staple.

14. (Original) The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a two-part fastener.

15. (Original) The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a suture.

16. (Original) The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a T-bar suture.

17. (Original) The tissue shaping instrument of claim 5 wherein either or both the first tissue engaging device and the second tissue engaging device is non-piercing.

18. (Previously Presented) The tissue shaping instrument of claim 5 wherein at least part of the elongated member is flexible.

19. (Original) The tissue shaping instrument of claim 5 further comprising a viewing endoscope.

20. (Original) The tissue shaping instrument of claim 5 further comprising at least one working channel.

21. (Original) The tissue shaping instrument of claim 5 wherein the instrument is sterilized.

22. (Cancelled).

23. (Cancelled).

24. (Previously Presented) An apparatus, comprising:

means for transorally engaging a plurality of regions of stomach tissue with a plurality of members from within the stomach, at least one of the members configured to move toward another member to reconfigure tissue, wherein the plurality of members include a first member positioned on a central longitudinal axis and having a first securing part configured to engage a first stomach tissue section and a second member positioned on a central longitudinal axis and having a second securing part configured to engage a second stomach tissue section, the first and second members being positioned on the same central longitudinal axis, said means comprising an actuating mechanism operatively linking the first and second members to facilitate simultaneous independent movement of said members to draw together the first and second stomach tissue sections; and

means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue.

25. (Previously Presented) The apparatus of claim 24 wherein the first securing part and the second securing part comprise tissue engaging means.

26. (Previously Presented) The apparatus of claim 25 wherein the tissue engaging means includes a corkscrew element.

27. (Previously Presented) The apparatus of claim 25 wherein the tissue engaging means includes a clamping device.

28. (Previously Presented) The apparatus of claim 25 wherein the tissue engaging means includes a suction device.

29. (Previously Presented) The apparatus of claim 25 wherein the tissue engaging means includes a grasping device.

30. (Original) The apparatus of claim 25 further comprising a means for securing the reconfigured tissue.

31. (Original) The apparatus of claim 30 wherein the securing means includes one or more of: a staple, a clip, a tack, a rivet, a two-part fastener, a helical fastener, a suture, a T-bar suture, and a tissue adhesive.

32. (Original) The apparatus of claim 30 wherein the securing means is biocompatible.

33. (Original) The apparatus of claim 30 wherein the securing means is non-resorbable.

34. (Previously Presented) Apparatus comprising: a substantially rigid elongated member configured for transoral placement in the stomach and having a distal region including first and second movable members configured to be moved toward one another to reconfigure stomach tissue, the first movable member being positioned on a central longitudinal axis and the second movable member being positioned on a central longitudinal axis, the distal region being steerable as a unit, and means for deploying an implant from at least one of the members to secure the reconfigured tissue, wherein the first and second movable members are positioned on the same longitudinal central axis.

35. (Original) The apparatus of claim 34 wherein the first movable member includes a first

securing part configured to engage a first tissue section and the second movable member includes a second securing part configured to engage a second tissue section.

36. (Original) The apparatus of claim 34 wherein the elongated member includes a corkscrew element.

37. (Original) The apparatus of claim 34 wherein the elongated member includes a clamping device.

38. (Original) The apparatus of claim 34 wherein the elongated member includes a suction device.

39. (Original) The apparatus of claim 34 wherein the elongated member includes a grasping device.

40. (Original) The apparatus of claim 34 wherein the deploying means includes a distal end effector configured to contact the reconfigured stomach tissue.

41. (Original) The apparatus of claim 40 wherein the distal end effector includes at least one tissue fixation device.

42. (Original) The apparatus of claim 41 wherein the distal end effector is configured for application of the at least one tissue fixation device into the reconfigured stomach tissue.

43. (Original) The apparatus of claim 40 further comprising a means for controlling the distal end effector.

44. (Original) The apparatus of claim 43 wherein the controlling means is disposed at a proximal end of the apparatus and is operatively connected to the distal end effector.

45. (Previously Presented) The tissue shaping instrument of claim 1, further comprising:

a first actuating mechanism cooperating with the first tissue engaging device, said first actuating mechanism being controllable by a user at said proximal controlling portion; and

a second actuating mechanism cooperating with the second tissue engaging device operatively linking the articulable arms to facilitate simultaneous dependent movement of said arms, said second tissue engaging device being controllable by a user at the proximal controlling portion.

46. (Previously Presented) The tissue shaping instrument of claim 45, wherein the first actuating mechanism comprises a control cable cooperating with a biasing member.

47. (Previously Presented) The tissue shaping instrument of claim 46, wherein the biasing member is a torsion spring.

48. (Previously Presented) The tissue shaping instrument of claim 45, wherein the second actuating mechanism comprises a biasing member acting between said articulable arms and a pair of control cables cooperating with said biasing member.

49. (Previously Presented) The tissue shaping instrument of claim 1, further comprising a tissue grasper disposed on a distal end of the articulable arm opposite said tissue piercing element.

50. (Previously Presented) The tissue shaping instrument of claim 1, further comprising a suction device disposed on a distal end of the articulable arm opposite said tissue piercing element.

51. (Previously Presented) The tissue shaping instrument of claim 1, further comprising a tissue piercing element at the distal end of each said articulable arm.

52. (Previously Presented) The tissue shaping instrument of claim 51, wherein said tissue piercing elements comprise a coil with a sharp distal tip.

53. (Previously Presented) An apparatus, comprising:

a plurality of tissue engaging members having at least a first member positioned on a central longitudinal axis and having a first securing part configured to engage a first stomach tissue section and at least a second member positioned on a central longitudinal axis and having a second securing part configured to engage a second stomach tissue section, the first and second members being positioned on the same central longitudinal axis; and

an actuating mechanism operatively linking the first and second members to facilitate simultaneous independent movement of the members to draw together first and second stomach tissue sections,

wherein the apparatus is configured for transorally engaging a plurality of regions of stomach tissue with the plurality of members from within the stomach and wherein at least one of the members is configured to move toward another member to reconfigure tissue.

APPENDIX B: EVIDENCE

No attached evidence.

APPENDIX C: RELATED PROCEEDINGS

No related proceedings.

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